Decision Memo for Clinical Trial Policy (CAG-00071R)

Decision Summary

.

Back to Top

Decision Memo

TO: Administrative File: CAG-00071R
Clinical Trial Policy

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SUBJECT: Decision Memorandum for the Clinical Trial Policy

In 2000, CMS published the Clinical Trial Policy (CTP) National Coverage Determination (NCD) in response to a Presidential Executive Memorandum concerning payment for routine costs incurred by Medicare beneficiaries participating in clinical trials. That policy was based on the statutory authority of Section 1862(a)(1)(E) of the Social Security Act.

In July 2006, CMS began a reconsideration of that 2000 NCD to address several issues about the policy. After the publication of our proposed decision memorandum on April 10, 2007, we received several comments from hospitals and advocates suggesting that Medicare contractors had been paying claims for hospital services involving patients in various types of clinical trials outside the terms of the 2000 CTP. While hospitals may not have always identified these services as clinical trial services and these trials may have included comparative trials of products or drugs that had already been approved for one indication, the hospitals and others have sought assurances that coverage will continue for the usual patient care associated with research in a hospital.

The commenters have identified additional Medicare policies and statements that are not identical to the coverage provided under the proposed April 10, 2007 CTP and the existence of these policies may have been confusing or ambiguous. We intend to amend our policies so that they are clear and consistent in terms of our coverage. We recognize, however, that the public has not had an adequate opportunity to comment on those changes. Given the confusion about the 2000 CTP and some contractors' practice of paying claims of certain providers that did not meet those standards, we are issuing this national coverage determination in order to preserve the status quo with the exception of the two changes described below.

First, we are modifying the language in the 2000 CTP that could be read to restrict payment for the item or service under investigation, to the extent that the item or service would be covered outside of the clinical research trial. This language may have created ambiguity in the public's mind as to whether that meant even if the item or service under investigation was covered outside the trial. Therefore, we are modifying this language to make clear that such items or services would be covered if they would be covered outside of the clinical research trial.

Second, we are adopting the proposed addition of Coverage with Evidence Development (CED) to the 2000 CTP. CED is for items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination. CED is determined through the NCD process, and is conditional on meeting standards for clinical research that ensures patient protection and the development of evidence to evaluate coverage. Strong support for this was received from our Medicare Evidence Development& Coverage Advisory Committee and the Federal panel convened by AHRQ. Three comments addressed the CED process. They were from members of industry and a research institute. All were supportive of the concept and requested clarification of the interaction between CED and the CTP. One commenter requested additional information regarding how CED will impact the Agency setting research priorities, developing frameworks for study designs, and implementing the data collection and clinical study activities. We cannot respond to this request because we cannot predict the emergence of promising items or services, and the types of clinical research protocols necessary for their evaluation. While supportive, commenters encouraged CMS to be aware of the burden CED could potentially place on providers, practitioners, beneficiaries and sponsors/investigators. They were principally concerned with the additional expenditures that will be required of sponsors to comply with CED and further requested that CMS provide coverage for administrative costs when CED is required.

While we appreciate the additional burden that a trial adds to patient care, coverage under CED is for items and services that would not be covered otherwise. Thus, we believe that the benefits of adding this coverage under CED outweigh the burden and otherwise non-covering the item or service. Therefore, we will add CED to the CTP, whereby items and services furnished to Medicare beneficiaries under CED are reasonable and necessary.

Finally, in addition to this final NCD, we are reopening a reconsideration of the clinical trial policy NCD and issuing a new proposed national coverage determination to define a clear path to continued payment for clinical trials so that providers, practitioners, and suppliers can be assured of the circumstances in which Medicare payment will be available. We also expect shortly to propose changes to the regulations that pertain to clinical trials and Medicare payment and to implement changes to claims processing instructions. Our goal is to ensure that Medicare patients who voluntarily participate in medical research are appropriately protected and that Medicare support of research will produce information that is valuable for providers, practitioners, and suppliers as well as for future patients who will need to make health care decisions for similar medical conditions.

In summary, effective July 9, 2007, we will add the following to the Clinical Trial Policy:

The Centers for Medicare & Medicaid Services, through the national coverage determination (NCD) process, through an individualized assessment of benefits, risks, and research potential, *may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a "reasonable and necessary" determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.*

We will also add to the end of the first bullet point the phrase:

"unless otherwise covered outside of the clinical trial."

Medicare National Coverage Determinations Manual

310.1ROUTINE COSTS IN CLINICAL TRIALS

Effective for items and services furnished on or after September 19, 2000, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or servicein particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies or the regulations on categoryB investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.

For noncovered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the noncovered item or service and unrelated reasonable and necessary care. (Refer to MCM §§2300.1 and MIM 3101.) However, if the item or service is not covered by virtue of a national noncoverage policy in the Coverage Issues Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the noncovered item or service, itself, will not.

A. Requirements for Medicare Coverage of Routine Costs.Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

1.

The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

2.

The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

3.

Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1.

The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

2.

The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

3.

The trial does not unjustifiably duplicate existing studies;

4.

The trial design is appropriate to answer the research question being asked in the trial;

5.

The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

6.

The trial is in compliance with Federal regulations relating to the protection of human subjects; and

7.

All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

B. Qualification Process for Clinical Trials.Using the authority found in §1142 of the Act (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to HCFA.

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1.

Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA;

2.

Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;

3.

Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and

4.

Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

CMS, through the national coverage determination (NCD) process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, ~~or~~ have certified that they meet the qualifying criteria, or are required through the NCD process unless HCFA's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should HCFA find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

Medicare regulations require Medicare+Choice (M+C) organizations to follow HCFA's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

Back to Top